

Remarks

Claims 1 and 8 are amended. Claims 1-20 will be pending upon entry of this amendment.

Amendments to the Specification

The Specification is amended to include a more detailed discussion of features that are clearly shown in the drawings but not described in detail in the written description. More specifically, the Specification is amended to add details of the body of the radioulnar component, including the arms (57A, 57B) and base (57C) of the component. The Specification is also amended to more precisely describe the location of the bore (62) in the second arm of the radioulnar component and the location of the bore (102) in the olecranon process (OP) of the ulna (U).

In describing the screw, which is not shown, the term "anconeal" is replaced with the term - olecranon - because, as shown in Fig. 1, the screw hole (102) for receiving the screw extends through the olecranon process of the ulna, not the anconeal process. Therefore, one skilled in the art would recognize that the use of the term olecranon is more descriptive of the function of the screw originally described in the application, than the term anconeal.

No new matter is being added by the additions to the specification as the subject matter being described is clearly shown in the drawings.

Amendments to the Drawings

The drawings are amended to include additional reference characters, as reflected by the changes to the specification. No other changes to the drawings are being made.

No new matter is being added.

Summary of Amendments to the Claims

Independent claims 1 and 8 are amended to further define the invention as being a prosthetic elbow for an animal, such as a canine. More specifically, claims 1 and 8 are amended to recite a bore extending longitudinally within a second arm of the radioulnar component. As described in the specification, the bore in the radioulnar component allows for a screw to be inserted through the olecranon of the ulna and into the radioulnar component to provide immediate rigid fixation of the radioulnar component to the ulna. The immediate rigid fixation of the radioulnar component to the ulna ensures appropriate axial alignment of the prosthesis and contributes to the stability of the implant allowing immediate and prolonged weight-bearing through the prosthesis. It is important that the elbow prosthesis for the animal provide immediate weight-bearing capabilities after surgery because it will be very difficult if not impossible to keep the animal off its legs after surgery.

Response to Rejection of Claim 1 under 35 USC §102

Claims 1 and 8

Claim 1 is now directed to a prosthetic elbow comprising, in pertinent part:

a radioulnar component comprising

a body having a base and a pair of spaced apart, first and second arms extending outward from the base...

a peg sized and shaped for being received in an axial bore in the ulna...

wherein the second arm of the body has a bore extending longitudinally therein in a direction generally orthogonal to the peg, the bore being sized and shaped for

receiving a fastener inserted in an olecranon process of the ulna generally transverse to the longitudinal axis of the ulna to secure the radioulnar component to the ulna.

Claims 1 and 8 are amended to more specifically define structure of the radioulnar component of the prosthetic elbow that distinguishes the present invention from the prior art. More specifically, claims 1 and 8 are amended, in pertinent part, to recite that the radioulnar component has a first and second arms, a peg extending laterally outward from the first arm generally transverse to the first arm, and a bore extending longitudinally in the second arm of the radioulnar component generally orthogonal to the peg and sized and shaped for receiving a fastener that is inserted in an olecranon of the ulna. As explained above in the "Summary of Amendments to the Claims", the bore in the second arm allows for the radioulnar component to be immediately fixed to the ulna, which ensures appropriate axial alignment of the prosthesis and contributes to the stability of the implant allowing immediate and prolonged weight-bearing through the prosthesis instead of waiting for cement to harden before bearing weight.

Neither the primary reference of record, GB 1 528 906 (Dee), nor the other references of record shows or suggests a component comprising a peg extending generally transversely from an arm of the component and having bore extending longitudinally through another arm of the component generally orthogonal to the peg of the component for receiving a fastener extending through an olecranon of the ulna. Dee teaches only a stem (32) and the use of cement to secure an ulnar component (30) to an ulna. There is no bore through the bearing member (31).

Moreover, there is no teaching or suggestion in Dee or the other the references of record to modify the radioulnar component in Dee so that one of the arms has such a longitudinal bore. As stated above, the bore in the radioulnar component allows for immediate stability and weight-bearing because a screw can be inserted through the olecranon and into the bore. Neither Dee nor the other references of record show or suggest such a feature. Further, as can be seen best looking at Fig. 9, any bore extending longitudinally through the arm of the C-shaped bearing member (31) would not be generally orthogonal to the stem (32).

The other references of record similarly fail to show or suggest all of the elements of claims 1 and 8.

For these reasons, claims 1 and 8 as amended are submitted to be patentable over the references of record.

Claims 2-7, 9-15 and 20 depend directly or indirectly from either claim 1 or claim 8 and are submitted to be patentable for the same reasons as claims 1 and 8.

Claim 20

In addition to being patentable for the same reasons as claim 1, claim 20 is further distinguishable over the prior art, and in particular, Dee, in that the references of record do not show or suggest a component of a prosthetic elbow that is adapted for attachment to **both** the ulna and the radius. Instead, Dee teaches a radial component (40) and an ulnar component (30).

Further, there is no suggestion or motivation to modify the prosthesis in Dee to make a radioulnar component for attaching to both the ulna and the radius. As with claim 1, the feature of the radioulnar component recited in claim 20 is based on a

difference between the elbow of a human and the elbow of a four-legged animal, such as a canine. As shown in Dee and as is known by those having ordinary skill in the art, prosthetic elbows for humans are designed to maintain the articulation between the ulna and the radius to allow pronation and supination of the forearm. Thus, as taught by Dee, the prosthetic elbow requires separate ulnar (30) and radial (40) components to maintain articulation between the ulna and radius. As described in the present invention, the radioulnar component makes a true hinge joint (paragraph [0022]). The true hinge joint allows for immediate and prolonged fusion between radius and ulna, contributes to the alignment and stability of the implant and allows for immediate and prolonged weight-bearing through the prosthesis.

Accordingly, there is no suggestion or motivation for one skilled in the art to modify the teachings of Dee to make a radioulnar component for attachment to both the radius and the ulna.

Claim 16

New claim 16 is directed to a prosthetic elbow including, among other things, a humeral component having a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, wherein the humeral component is free of a stem for extending into a medullary canal of the humerus and the humeral component comprises a stabilizer extending axially from the spool for engaging the humerus to prevent rotation of the spool about the bore. This claimed construction allows for the spool to be fixedly attached to the humerus using the axial bore and the stabilizer without reaming

the medullary cavity of the humerus to insert a stem of the humeral component. Accordingly, the surgery is less complicated and less invasive than surgery involving a humeral component with a stem.

More specifically, claim 16 recites a prosthetic elbow for attachment to a humerus and ulna comprising:

a humeral component comprising a generally cylindric spool having a contoured external surface defining a first articular surface;

a radioulnar component comprising a body having a generally U-shaped contour with an inner peripheral surface defining a second articular surface sized and shaped for engagement with the first articular surface;

wherein the humeral component has a bore extending axially through the spool for receiving at least one fastener to attach the humeral component to the humerus, the humeral component being free of a stem for extending into a medullary canal of the humerus, the humeral component comprising a stabilizer extending axially from the spool for engaging the humerus for fixation and prevention rotation of the spool about the bore.

The present Office action fails to point out each and every element of claim 16 that is found in Dee. More specifically, the Examiner has failed to point to anywhere in Dee that teaches the feature of a stabilizer extending axially from the spool for engaging the humerus for fixation and preventing rotation of the spool about the bore. Examples of such an axially extending stabilizer are a peg (122; Fig. 13) - and a panel (132; Fig. 14). Further, there is no suggestion or motivation in any of the references for modifying the ulnar component (30) so that it includes a stabilizer.

The other references of record similarly fail to show or suggest all of the elements of claim 16.

For these reasons, claim 16 is submitted to be patentable over the references of record.

Claims 17-19 depend either directly or indirectly from claim 16 and are submitted to be patentable over the references of record for at least the same reasons as claim 16.

Conclusion

In view of the foregoing, favorable consideration and allowance of claims 1-20 is respectfully requested.

It is believed that a 3-month extension fee of \$525.00 is due regarding this response. Please charge this fee to Deposit Account No. 19-1345. The Commissioner is hereby authorized to credit any overpayment or charge any underpayment of Government fees to Deposit Account No. 19-1345.

Respectfully submitted,

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